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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,490	09/29/2003	Kwang Hyo Chung	123034-05004739	8465

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EXAMINER

NAGPAUL, JYOTI

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

21

Office Action Summary	Application No.		Applicant(s)	
	10/671,490		CHUNG ET AL.	
	Examiner		Art Unit	
	Jyoti Nagpaul		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment filed on January 24, 2006 has been acknowledged. Claims 1-17 are pending.

Election/Restrictions

Newly submitted claim 17 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- I. Claims 1-16, drawn to a device for controlling fluid, classified in class 422, subclass 100.
- II. Claim 17, drawn to method for controlling fluid, classified in class 436, subclass 180.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, for example, a process that does not require a stopping barrier.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 17 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

Rejection of Claims 1-8 as being anticipated by Buechler (US 6271040) has been modified in light of applicant's amendments.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-8 and 11-16** are rejected under 35 U.S.C. 102(b) as being anticipated by Buechler (US 6271040).

Buechler teaches an assay device which comprises flow control elements, measurement elements and time gates. (See Abstract) The device includes at least one storage chamber/sample addition zone (1) to which a fluid is injected and stored; at least one reaction chamber (4) in which a predetermined reaction is occurring with the fluid; at least one exhaust chamber (7) into which the used fluid is exhausted; at least one side connecting channel (See Figure 1) which connects at least two stop valves/fingers (16) wherein the stop valves stop the flow of the fluid using surface tension of the fluid; Buechler teaches, " at least one flow delay part/sample reaction

barrier (3) which is formed within connecting channel and delays flow of the fluid by the surface tension of the fluid; and at least one stop valve/time gate (5) which is formed within connecting channel (See Figure 1) and stops the flow of the fluid by surface tension. Buechler teaches, "the time gate 5 holds the reaction mixture in the reaction chamber 4 for a given period of time. The concept of the time gate is that a predominantly aqueous solution cannot pass through a sufficiently hydrophobic zone until the hydrophobic zone is made sufficiently hydrophilic. Furthermore, the hydrophobic zone is made hydrophilic through the binding of a component in the aqueous solution to the hydrophobic zone." (See Col. 11, Lines 15-15-21) The fluid moves from the storage chamber/sample addition zone (1) to the reaction chamber (4) and exhaust chamber (7) by means of the surface tension while exchange of the fluid naturally occurs in the reaction chamber (4). Buechler teaches, "Fluid flow on a surface or in a capillary is affected by the surface tension of the fluid." (See Col. 27, Lines 61-62) The at least one connecting channel adjusts the surface tension by increasing or decreasing a width of the path or by performing surface modification or temperature change so that the fluid reliably moves. Buechler teaches, "For example, in a capillary channel that is formed by essentially planar walls that intersect along corners, fluid flow preferentially precedes along the corners. The predisposition for fluid flow to proceed at corners occurs because the corners of a capillary create the lowest surface tension for the fluid." (See Col. 27, Lines 62-67) (See Figure 1) The flow delay part/sample reaction barrier (3) adjusts the surface tension by having hydrophilic or hydrophobic property through a channel surface of the valve, deforming the channel geometry or

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changing a temperature of the channel surface of the valve. (See Figure 1) The at least on exhaust chamber (7) includes a structure which keeps the flow of the fluid smooth by increasing the surface tension and makes the preceding portion of the fluid uniform when the fluid flows to prevent fine air bubbles from occurring. Buechler teaches, "when a uniform flow front is required within a capillary, the reduced surface tension at comers of the capillary can cause a non-uniform flow front. Non-uniform flow fronts can result in the creation of air pockets within the capillary. If air pockets occur, wetting of the capillary surfaces within the air pocket is impaired or prevented.

Embodiments of this invention which comprise hydrophobic areas on a lumenal surface of a capillary space act to control fluid flow within capillaries, and more specifically to minimize fluid flow at the corners of capillaries so that the fluid flow front is convex rather than concave." (See Col. 28, Lines 1-21) The at least one connecting channel includes an isolation threshold to prevent reactant among plurality of the reaction chamber (4) from diffusing. Buechler teaches, "The volume of sample which fills the sample-reaction barrier 3 (FIG. 1A) should be kept to a minimum, from about 0.01% to 10% of the reaction chamber 4 volume so that the reagents of the reaction chamber 4 do not significantly diffuse back into the sample in the sample addition reservoir 2. That is, the diffusion of the reaction mixture back into the excess sample should be kept to a minimum so that the chemical or biochemical reactions occurring in the reaction mixture are not substantially influenced by the excess sample in the sample addition reservoir 2." (See Col. 9, Lines 32-41) Buechler further teaches, "The biosensor comprises an optical transducer." (See Claim 3) Buechler further teaches a filter. Buechler teaches,

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"A filter element can be placed in or on the sample addition reservoir 2 to filter particulates from the sample or to filter blood cells from blood so that plasma can further travel through the device" (See Col.8, Lines 35-37) Buechler further teaches a sample preparation chamber (2). Buechler further teaches at least one air vent. Buechler teaches, "The device can comprise an inlet port and a vent". (See Col. 4, Lines 40-41) With respect to Claims 14-16, examiner would like to point out that no structural elements are further limiting the apparatus to meet these limitations. Buechler meets the structural limitations and clearly is capable of being a drug delivery device, biochip and micro biological/chemical reactor.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 9 and 10** are rejected under 35 U.S.C. 103(a) as being obvious over Buechler.

Refer above for the teachings of Buechler.

Buechler fails to explicitly disclose at least two devices connected in series and parallel.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to connect at least two of the devices in series and parallel in order to increase to conduct multiple analysis in a single run, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Response to Arguments

Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection. Please refer above.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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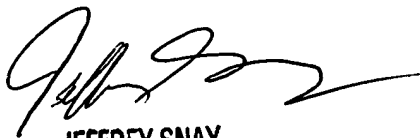
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN



JEFFREY SNAY
PRIMARY EXAMINER